

CLAIMS

5 1. Polymorphic Form E of base ondansetron, characterised in that its powder X-ray diffraction pattern presents characteristic peaks at 6.29°; 11.09°; 11.88°; 12.69°; 14.97° and a doublet at (24.96°; 25.17°) 2θ.

10 2. Polymorphic form according to Claim 1, characterised in that its powder X-ray diffraction pattern presents the following peaks:

2θ (°)
6.29
7.06
10.50
11.09
11.88
12.69
13.10
13.57
14.97
16.33
16.93
17.40
18.58
19.28
20.71
21.08
21.28
22.10
24.12
24.71
24.96
25.17
25.73
26.65
26.93
28.18
28.53
29.34
29.76

3. Polymorphic form according to Claim 2, characterised in that it presents a powder X-ray diffraction pattern in accordance with Figure 1.

5 4. Process for preparing the polymorphic form according to Claim 1, characterised in that it comprises:

- a) dissolution of the ondansetron hydrochloride in a mixture of a C₁-C₃ alcohol and water;
- b) precipitation of the base ondansetron by basification 10 of the solution;
- c) filtering the solid and washing with water;
- d) suspension of the water-moistened solid obtained in stage c) with methanol at reflux with stirring; and
- e) recovery of the crystalline form;
- 15 f) and filtering and drying the product thus obtained.

5. Process according to claim 4, characterised in that said alcohol is methanol.

20 6. Process according to Claim 4, characterised in that the basification of stage b) is carried out by addition of an aqueous ammonia solution.

7. Pharmaceutical composition that includes a 25 polymorphic form according to claim 1, in a therapeutically active amount and with a suitable amount of at least one excipient.

8. A polymorphic form according to claim 1 for use 30 for manufacturing a drug for the treatment and prophylaxis of post-operative nausea and vomiting and for the control of nausea and vomiting induced by radiotherapy and cytotoxic chemotherapy.